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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,178	09/30/2003	Marco Pinna	243129US0	1258

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EXAMINER
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ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
09/12/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/673,178	PINNA ET AL.	
	Examiner	Art Unit	
	Susan E. Fernandez	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed May 29, 2007, has been received and entered.

Claims 1-9 are pending. Claim 7 is withdrawn. Claims 1-6, 8, and 9 are examined on the merits to the extent they read on the elected subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Xu et al. (US 6,419,903).

Xu et al. discloses a "rapidly dissolvable orally consumable film composition" comprising "water soluble, low viscosity hydroxyalkylmethyl cellulose and water dispersible starch and a flavoring agent" (abstract).

Xu et al. teaches that the cellulose is present in the film composition in an amount ranging from about 10 to about 60% by weight (column 3, lines 8-11), which meets the cellulose weight requirements recited in instant claim 1. Further still, Xu et al. teaches that the hydroxyalkylmethyl cellulose may be hydroxypropyl methyl cellulose (claim 2), thus meeting limitations in instant claims 1 and 4.

The pregelatinized starch in the film composition is present in an amount ranging from about 5 to about 50% by weight (column 3, lines 47-49), which fits within the weight range recited in instant claim 1.

The flavoring agent can be considered a cosmetic, aromatic, pharmaceutical and/or food substance. Moreover, this flavoring agent is present in the film composition in an amount ranging "from about 2.0 to about 10% by weight" (column 4, lines 3-6). Given that "about 10%" embodies percentages above 10%, such as 10.1%, the Xu invention clearly anticipates instant claim 1 which requires an active substance in an amount of from 10 to 50% by weight relative to the total weight of the film composition. Moreover, the composition can further comprise active breath freshening agents (column 4, line 40-42) which may be present in the composition at a concentration of about 0.1 to about 2.0% by weight (column 4, lines 46-49). These breath freshening agents can be considered additional active substances, thus contributing to the amount of active substances present in the film composition. Even if the flavoring agent were present in amount of 10% by weight of the composition, the presence of the breath freshening agents result in a composition comprising active substances in a concentration of more than 10% by weight of the composition.

Xu et al. also teaches that the film composition quickly dissolves in the mouth and "...generally in less than 30-40 seconds" (column 2, lines 57-58). Thus, the film composition can dissolve at lengths of time shorter than 30-40 seconds, including 10 seconds and 7 seconds. Moreover, lengths of time shorter than 30-40 seconds can be considered a dissolution time of "a few seconds." Thus, the Xu invention meets the dissolving time limitations recited in instant claims 1, 8, and 9.

Finally, in the preparation of the Xu invention, the starch forms a homogeneous mixture with cellulose (column 4, lines 54-63). Thus, the starch binds to the cellulose in a stable form.

A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. in view of Hata (US 4,345,032) and Sharik (US 5,206,026).

As discussed above, Xu et al. anticipates claims 1, 4, 8, and 9. However, Xu et al. does not expressly disclose that bacteria is present in the disclosed composition.

Hata discloses that specific lactobacillus strains have the ability to deodorize foul breath (column 1, lines 42-45).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have substituted the flavoring agent of the Xu invention with specific lactobacillus strains appropriate for deodorizing foul breath. One of ordinary skill in the art would have been motivated to do this since these lactobacillus strains would have served as breath freshening agents, as required by the Xu invention.

Xu et al. also differs from the instant invention in that it does not teach a composition comprising hydroxyethyl cellulose or hydroxypropyl cellulose.

Sharik discloses an instantaneous delivery film for the delivery of a therapeutic agent (abstract), wherein the delivery film comprises of a film-forming polymer which must be water soluble (column 3, lines 15-27). Suitable film-forming polymers include hydroxyethyl cellulose and hydroxypropyl cellulose.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have modified the Xu invention such that hydroxyethyl cellulose or hydroxypropyl cellulose is used as the cellulose of the Xu invention. One of ordinary skill in the art would have been motivated to do this since these celluloses would have enabled the formation of a film. Thus, a holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments filed May 29, 2007, have been fully considered but they are not persuasive. Applicant asserts that the formation of a homogeneous mixture disclosed in Xu et al.

when combining a cellulose and a starch does not constitute a disclosure of at least one starch and at least one cellulose compound being "bound in stable form" as required by claim 1. The applicant further highlights that for the definition of a mixture, two or more substances are not chemically combined with each other. However, it is respectfully noted that the claims under examination do not require that the at least one starch and the at least one cellulose are **chemically** bound to one another. The Random House College Dictionary (Revised Edition, 1980) defines "bound" as "held with another element, substance, or material in chemical or physical union." As starch and cellulose in the Xu invention are in a homogeneous mixture, the two compounds are in a physical union, and are thus bound to each other, in stable form.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., starch and cellulose bound in stable form by successive heating and cooling under agitation; reaction between hydroxyl groups of the cellulose and hydroxyl and carboxyl groups of the starch) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant also asserts that an edible film including at least one starch and at least one cellulose compound bound in stable form is capable of retaining a greater amount of active substance and dissolving at a faster rate than known edible films. First, it is noted that the feature of retention of a greater amount of active substance than known edible films is not recited in the claims under examination. With respect to the dissolution time of the Xu invention, as pointed out in the previous office action, Xu et al. states that the dissolution time is "...generally

in less than 30-40 seconds" (column 2, line 58, emphasis added) and not in a time of from about 30 to 40 seconds. Moreover, applicant has not provided any evidence to demonstrate that the recited dissolution time of less than 30-40 seconds is indeed aspirational. Finally, it is noted that the instant claims no longer recite that the starch is of low molecular weight and high amylopectin content.

Given that Xu et al. anticipates the claimed invention, the rejections of record over Xu et al. in view of Hata and Sharik must be maintained.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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